IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Howard J. Worman and Naoto Mamiya

Serial No. : 09/407,432

Filed : September 29, 1999

For : A HCV CORE PROTEIN BINDING AGENT FOR TREATMENT OF HEPATITIS C VIRUS INFECTION

1185 Avenue of the Americas
New York, New York 10036

January 19, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO DECEMBER 19, 2000 RESTRICTION REQUIREMENT

This is a Response to the Restriction Requirement issued December 19, 2000 in connection with the above identified application. A response to the December 19, 2000 Restriction Requirement is due on January 19, 2001. Accordingly, this Response is being timely filed.

In the December 19, 2000 Restriction Requirement, the Examiner required restriction to one of the following allegedly distinct invention as follows:

I. Claims 20-32 and 45, drawn to screening assay for inhibitory compounds;

II. Claims 1-19, drawn to HCV treatment method; and

III. Claims 70-71, drawn to cancer treatment composition.

The Examiner alleged that the inventions are distinct, each from the other, because they are unrelated. In the instant case the Examiner alleged that the different inventions are unrelated because they are not used together, and have different modes of operation, different functions, and different effects. Specifically, the Examiner noted that while invention I used HCV core plus a second compound to detect inhibitory activity of a third compound, invention II used HCV-core-binding material to treat or prevent infection in vivo, and invention III used HCV protein to inhibit cancer cell growth.

Alleging these inventions are distinct for the reasons given above and have acquired separate status in the art because of their recognized divergent subject matter, the Examiner asserted that restriction for examination purposes as indicated in proper.

In response, applicants hereby elect, with traverse, Group II, claims 1-19. Within Group I, applicants elect for initial examination the DEAD-box protein, but look forward to a full examination of all species pursuant to M.P.E.P. §809.02(c).

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

The inventions of Groups I, II, and III are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed

relationship between the subjects disclosed. The inventions of Groups I, II, and III are all relate to a method of treating or preventing hepatitis C virus infection in a subject. Applicants therefore maintain that the Groups are not independent and restriction is not proper.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: 1) the invention must be independent and distinct, **and** 2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required, because a search of the prior art relevant to any of the claims of Group I would necessarily turn up the prior art relevant to the claims of Groups II and III, and *vice versa*. Since there is no burden on the Examiner to examine Groups I-III together in the subject application, the Examiner must examine the entire application on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121 and respectfully requests that the Examiner reconsider and withdraw the requirement for restriction.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is

hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

1/19/01

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